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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/426,931	10/22/1999	WOLFGANG-REINHOLD KNAPPE	BMID9826US	2537

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EXAMINER	
CROSS, LATOYA I	
ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 01/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/426,931	KNAPPE, WOLFGANG-REINHOL	
	Examin r	Art Unit	
	LaToya I. Cross	1743	

-- Th MAILING DATE of this communication appears on the cov r she t with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 December 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *41-48 and 56-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *56* is/are allowed.

6)☒ Claim(s) *41-43,46-48 and 57-60* is/are rejected.

7)☒ Claim(s) *44 and 45* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

This Office Action is in response to Applicants' After-Final amendment filed on December 4, 2003. The After Final amendment has been entered into the record. Claims 41-48 and 56-60 are pending.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 41-43, 57-60 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 5 of U.S. Patent No. 6,537,496. Although the conflicting claims are not identical, they are not patentably distinct from each other because, the patented claims recite an N-acyl-N-alkyl-glycinate as the wetting agent. The disclosure of the patent specifically defines N-oleoyl sarcosinate as the preferred glycinate wetting agent. Thus, the claims of the patent are not distinguishable from the claims of the instant invention.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 41-43, 46-48 and 57-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Good et al in view of Dreyfus.

Good et al '224 teach a diagnostic test strip for determining the presence of a specified analyte in a fluid sample. The test strip has a test membrane sandwiched between two layers. The test membrane has a sample-receiving zone containing a buffer and a fatty acid sarcosinate. The sample-receiving zone (21) is a pad made of non-woven fibrous material, for example paper or polyurethane polymer material. The sample is absorbed by the pad, solubilizes the buffer and fatty acid sarcosinate and migrates to an adjacent reagent zone (22) containing reagent chemicals in fibrous matrix. The sarcsoinate is present in a concentration of about 1.0 % by weight. Good et al '224 also disclose that the sample-receiving zone is made by imbibing a solution containing a suitable buffer and fatty acid sarcosinate into a sheet to provide the appropriate concentration. See col. 4, lines 8-16 and col. 5, lines 8-27. With respect to the test fields recited in claims 41-43 and 46-48, Good et al '224 teach test layers comprising a test zone, control zone, reagent zone and sample receiving zone. The sample receiving zone is a fibrous pad containing the fatty acid sarcosinate wetting material. The sample receiving zone overlays the other zones (reagent, test and control), as recited in claim 41. Figure 3 shows the fields overlaying one another, as recited in claim 46. With respect to claim 47, Good et al teaches an inert plastic layer (31) having an aperture to allow sample application. With respect to claim 57, Good et al teach a further embodiment where the plastic encasing is removable.

Thus, the overlay (sample receiving zone) may be displaced from the detection zone and the remainder of the test strip.

Although Good et al '224 teach fatty acid sarcosinates as wetting agents, Good et al '224 fail to specifically teach the use of oleoyl sarcosinate as the wetting agent.

Dreyfus '987 teaches fatty acid sarcosine as good wetting agents. At col. 2, lines 20-30, Dreyfus teaches higher fatty acid radicals, such as those containing more than 8 carbon atoms are suitable. Dreyfus specifically teaches the oleic acid radical as an example where valuable results may be obtained. The fatty acid sarcosines are particularly used in wet treating textile materials such as fabric-like material.

It would have been obvious to one of ordinary skill in the art to use the oleoyl sarcosine wetting agents taught by Dreyfus in the test strips of Good to provide better wetting properties to the fibrous pads and allow sample to be up taken more efficiently.

With respect to the claims requiring specific weights and thickness of the fibrous material, such would be dependent on the type of sample and amount of sample needed to conduct the analytical test. The skilled artisan would have been able to determine a suitable weight and thickness for the particular sample being collected.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be obvious within the meaning of 35 USC 103 in view of the teachings of Good et al '224 and Dreyfus '987.

Allowable Subject Matter

5. Claims 44 and 45 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

6. Claim 56 is allowed.

The prior art of record fails to teach two overlay elements, as recited in claim 44, wherein the overlay elements face one another and whose parts are displaceable from the test strip. Further, with respect to claim 56, the prior art of record fails to teach a spreading material overlay larger than a test field and support on two sides of the test field by way of a spacer.

Response to Arguments

7. Applicant's arguments filed December 4, 2003 have been fully considered but they are not persuasive. In response to the rejection over Good et al in view of Dreyfus, Applicants argue that Good et al fail to teach that the overlay (sample receiving zone) has a liquid conducting capacity such that excess sample does not reach the detection layer. The Examiner would point out that Good et al use non-woven materials, such as paper or polyurethane in the sample receiving zone. The polyurethane material may have a pore size as small as 127 micrometers. Further, Good et al teach the incorporation of a fatty acid sarcosinate wetting agent into the non-woven material. See col. 5, lines 8-27 and lines 39-63. Applicant's specification describes the overlay material as possibly being a polymeric material, such as polyurethane, having a pore size of below 200 micrometers (specification page 12). The Examiner takes the position that because the sample receiving zone of Good et al is comprised of materials having properties similar to those used by Applicants, the sample receiving zone of Good et al would have properties similar to those claimed, i.e. liquid conducting capacity to not allow excess sample to reach the detection layer. It is noted that Good et al do teach the presence of a waste pad to catch excess sample, however, this does not necessarily mean that

there will be excess sample available to be caught by the waste pad. In fact, it seems that since the materials for the sample receiving zone of Good et al are so similar to those disclosed by Applicants, the sample receiving zone of Good et al would have a liquid conducting capacity equivalent to that of Applicants. With respect to claim 48, where Applicants recite that the hydrophilicity, transparency and liquid conducting capacity of the overlay are matched to not allow excess sample to be taken up, there is no showing or explanation in the specification to show what hydrophilicity, transparency or conducting capacity is sufficient to achieve this particular result.

With respect to claims 43 and 57, Applicants argue that Good et al disclose that the test strip and sample receiving zone are sealed on both sides by a plastic encasing – thus, the overlay cannot be freely displaced. Applicants' attention is directed to figure 5 of Good et al, showing an embodiment where the plastic encasing is hinged together and thus can be removed. In this embodiment, the sample receiving zone can be displaced from the remainder of the test strip.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 571-272-1256. The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1267.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Examiner.

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December 29, 2003

Jill Warden
Supervisory Patent Examiner
Technology Center 1700